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510(k) Summary

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1. Submitter InformationApplication Correspondent

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Date Prepared	December 31, 2010

Applicant

Company Name	FORA CARE Inc.
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2. Name of Device

Trade/Proprietary Name	FORA P30 Plus Multi-Mode Blood Pressure Monitoring System
Common Names	Blood pressure test system
Product Code	DXN
Classification Panel	Cardiovascular
Regulations	Class II, 21 CFR 870.1130

3. Predicate Device

Trade/Proprietary Name:	FORA P20 Blood Pressure Monitor
Common/Usual Name:	Blood pressure test system
Submitter	TaiDoc Technology Corporation
510 (k) Number	K092106

4. Device Description

The FORA P30 Plus Multi-Mode Blood Pressure Monitoring System uses the oscillometric method to measure the systolic, diastolic blood pressure and pulse rate with a inflatable arm cuff on adults.

The device has single measurement mode, averaging mode and auscultatory mode of blood pressure measurements. The single measurement mode functions like a regular blood pressure monitor. The averaging mode is selected for performing three consecutive measurements with a fixed resting period between each measurement and displays the averaged result on LCD. The auscultatory mode is selected for trained persons to measure with a stethoscope.

5. Intended Use

The FORA P30 Plus Multi-Mode Blood Pressure Monitoring System is a device intended to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual. The blood pressure is measured by using an inflatable cuff wrapped around the arm. This system should be used for the testing on people over age of 18.

The device detects the appearance of irregular heartbeat during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

6. Comparison to Predicate Device

The FORA P30 Plus Multi-Mode Blood Pressure Monitoring System and the predicate device both use the oscillometric method within the software algorithm to determine the systolic, diastolic blood pressure and pulse rate with a inflatable arm cuff. They all provide the auscultatory mode to allow trained persons to measure blood pressure with a stethoscope, and show a warning signal on LCD when detecting an irregular heartbeat (IHB). They both use traditional algorithm.

The major difference between the two devices is the physical appearance of device including outer casing design, printing and buttons. Minor software change includes the addition of the averaging mode that takes three consecutive measurements and displays the averaged result on the screen.

7. Performance Studies

The FORA P30 Plus Multi-Mode Blood Pressure Monitoring System was validated by the tests according to ANSI/AAMI SP10 and met the requirements of ANSI/AAMI SP10 for NIBP (non-invasive blood pressure).

Software validation was performed to verify and validate the system works functionally.

Testing performed also included electrical safety, EMC and biocompatibility. The proposed device met the requirements of IEC/EN 60601-1 and IEC/EN 60601-1-2. The materials of arm cuff met the requirements of ISO 10993-5 and 10993-10.

8. Conclusion

The FORA P30 Plus Multi-Mode Blood Pressure Monitoring System demonstrates the safety and effectiveness for its intended use. The FORA P30 Plus Multi-Mode Blood Pressure Monitoring System is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

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FORA CARE Inc.
c/o Teling Hsu
Regulatory Affairs Specialist, TaiDoc Technology Corporation
3F, 5F, 6F, No. 127, Wugong 2nd Rd.,
Wugu Township, Taipei County,
24888, Taiwan

Re: K110044

Trade/Device Name: FORA P30 Plus Multi-Mode Blood Pressure Monitoring System
(TD-3129)

Regulation Number: 21 CFR 870.1130

Regulation Name: Non invasive Blood Pressure Measurement System

Regulatory Class: Class II (two)

Product Code: DXN

Dated: June 24, 2011

Received: June 28, 2011

Dear Mrs. Hsu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

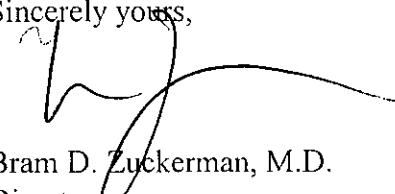
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 5**Indications for Use**

510(k) Number: k110044

Device Name: FORA P30 Plus Multi-Mode Blood Pressure Monitoring System

Indications for Use:

The FORA P30 Plus Multi-Mode Blood Pressure Monitoring System is a device intended to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual. The blood pressure is measured by using an inflatable cuff wrapped around the arm. This system should be used for the testing on people over age of 18.

The device detects the appearance of irregular heartbeat during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

Prescription Use _____

AND/OR

(21 CFR Part 801 Subpart D)

Over the Counter Use X

(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

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